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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/617,334	HAYDEN ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *1-23,29-40,46-48 and 50-56* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-28,41-45,49 and 57-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/10/03; 3/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 1-62 are pending in the application.

[2] Applicant's amendment to the claims, filed on 3/6/2006, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.

[3] Applicant's amendment to the specification, filed on 3/6/2006, is acknowledged.

[4] Applicant's response, filed on 3/6/2006, to the written restriction requirement mailed on 12/29/2005, is acknowledged.

[5] Receipt of an information disclosure statement, filed on 3/6/2006, is acknowledged.

Election/Restriction

[6] Applicant's election with traverse of Group V, claims 24-28, 41-45, 49, and 57-62 and the species of coronary artery disease, in the reply filed on 3/6/2006 is acknowledged. Applicant argues the claims of Group I should be rejoined with the claims of Group V on the ground(s) that there was an art-recognized correlation between cholesterol levels and coronary artery disease and in view of this correlation, the search for the inventions of Groups I and V would be substantially coextensive. The examiner acknowledges the specification's disclosure of a correlation between HDL-C levels and coronary artery disease. However, applicant's argument is not found persuasive because there is no evidence of record that one having a disorder of cholesterol metabolism (Group I) necessarily has cardiovascular disease (Group II) and

vice versa or that a disorder of cholesterol metabolism is necessarily symptomatic of cardiovascular disease and vice versa. Thus, it is false to assume that a prior art search for a cardiovascular disease will necessarily lead to prior art that teaches a disorder of cholesterol metabolism. Further, because each group recites a different disease, a search of each group would require independent considerations which would require the examiner to focus on different features and entail differently structured word searches for both patent and non-patent literature for each of the groups.

The requirement is still deemed proper and is therefore made FINAL.

[7] Claims 1-23, 29-40, 46-48, 50-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/6/2006.

[8] Claim 49 is being examined only to the extent the claim reads on the elected subject matter.

Priority

[9] Applicant's claim to domestic priority under 35 USC § 121 to US non-provisional application 09/526,193, filed on 3/15/2000, now US Patent 6,617,122, is acknowledged. Applicant's claim to domestic priority under 35 USC § 119(e) to US provisional applications 60/124,702, filed on 3/15/1999, 60/138,048, filed on 6/8/1999, 60/139,600, filed on 6/17/1999, and 60/151,977, filed on 9/1/1999, is acknowledged. The

specification amendment filed on 3/6/2006 perfects the priority claim. It is noted that the sequence of SEQ ID NO:1 appears to be first disclosed in application 60/138,048.

Information Disclosure Statement

[10] All references cited in the information disclosure statement filed on 3/3/2006 have been considered by the examiner. A copy of Forms PTO-1449 is attached to the instant Office action. All pages of the IDS filed on 7/10/2003 have been lined through as the references cited in the 7/10/2003 IDS are duplicated in the 3/3/2006 IDS.

Drawings

[11] When a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. See MPEP § 2422.02. See particularly Figures 4-6 and 14-15 of the drawings filed on 7/10/2003.

Specification/Informalities

[12] The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: -- Method for Treating a Mammal by Administering a Compound that Modulates the Biological Activity of ABC1 --.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[13] Claims 24-28, 41-45, 49, and 57-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 24, 27-28, and 61-62 recite the term "ABCA1 polypeptide." MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims." The disclosure of the specification uses the term "ABC1 polypeptide" and there is no indication in the specification or the prior art that an "ABCA1 polypeptide" is the same as an "ABC1 polypeptide," the reason for substituting "ABC1 polypeptide" with "ABCA1 polypeptide," or a showing of support for the term "ABCA1 polypeptide." MPEP § 2163 further states, "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

Thus, the recitation of "ABCA1 polypeptide" in the claims is considered to be new matter.

Also, new claims 57-62 were added in a preliminary amendment filed on 3/6/2006. Applicant points to pp. 1, 9, and 76 of the specification as supporting the newly added claims. The disclosure at p. 1 teaches a correlation between HDL-C and cardiovascular disease, the disclosure at p. 9 teaches a method for screening a compound for use in treatment of low HDL-C, and the disclosure at p. 76 teaches that agents that modulate ABCA1 biological activity or gene expression can be used to treat disorders such as cardiovascular disease or low HDL-C. In this case, the cited disclosure fails to support the claimed methods, which are drawn to the method of claim 25, wherein the cardiovascular disease "involves" a disorder of cholesterol metabolism. That the specification at p. 76 states that agents that modulate ABCA1 biological activity can be used to treat cardiovascular disease OR low HDL-C would appear to contradict applicant's assertion that this disclosure supports the claimed method. Applicant is invited to show support for the limitations of new claims 57-62.

[14] Claims 24-28, 41-45, 49, and 57-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method of treatment of a cardiovascular disease by administering a genus of compounds that modulate a biological activity of ABCA1. For claims drawn to a genus, MPEP § 2163 states the written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. MPEP § 2163 states that a representative number of species means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. In this case, the genus of compounds encompasses *any* compound that modulates any biological activity of ABCA1, including, *e.g.,* small molecule organic compounds, peptides, polypeptides, and antibodies. However, the specification fails to disclose even a single representative species of the recited compounds that can be used for *in vivo* treatment of a mammal having or at risk of developing a cardiovascular disease. While the prior art reference of Hamon et al. (*Blood* 90:2911-2915, 1997; cited as X1 in the IDS filed on 3/6/2006) discloses glyburide as an inhibitor of ABC1-mediated anion transport *in vitro* (p. 2911, right column, top) and further discloses glyburide, DIDS, and BSP as inhibitors of ABC1-

mediated IL-1beta transport *in vitro* (p. 2913, Figure 1 and p. 2914, Figure 3), these representative species fail to describe all members of the recited genus of compounds.

Given the lack of description of a representative number of compounds, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[15] Claim(s) 24-28, 41-45, 49, and 57-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP §

2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

The breadth of the claims: The claims are so broad as to encompass a method of treating a cardiovascular disease by administering a compound that has *any* structure, including any small organic compound, any peptide, any polypeptide, and any antibody, as long as it modulates any biological activity of ABCA1. It should be noted that the target of the compound is not limited to ABCA1. Thus, the compound can modulate biological activity of ABCA1 either directly or indirectly by altering the activities of, *e.g.*, transcription factors that regulate ABCA1 expression directly or indirectly or polypeptides that regulate the activity of ABCA1 or regulate the activity of polypeptides that regulate the activity of ABCA1.

The state of the prior art; The level of one of ordinary skill; The level of predictability in the art: At the time of the invention, neither the specification nor the prior art disclosed a compound that modulates ABCA1 activity that could be used therapeutically for treatment of a cardiovascular disease. Even after the time of the invention the art recognizes that therapies targeting ABCA1 for the treatment of coronary heart disease "has not yet been fulfilled" (Nofer et al. *Cell Mol Life Sci* 62:2150-2160, 2005; p. 2156, right column, bottom). While Nofer et al. acknowledges that "such treatments may be on the horizon," the reference also acknowledges that at least one potential therapy, namely LXR agonists, may cause gene changes that are detrimental (p. 2157, left column, top). In this case, the specification fails to set forth even a single compound that can be used to practice the claimed invention and, similar to the case in *University of*

Rochester v. GD Searle & Co., 375 F.3d 1303, 1304 (Fed. Cir. 2004), it is not routine to predict what compounds *might* bind to a polypeptide.

The amount of direction provided by the inventor; The existence of working examples: The specification fails to disclose even a single working example of a compound that modulates ABCA1 biological activity that can be used therapeutically for treatment of cardiovascular disease. As noted above, Hamon et al. (*Blood* 90:2911-2915, 1997; cited as X1 in the IDS filed on 3/6/2006) discloses glyburide as an inhibitor of ABC1-mediated anion transport *in vitro* (p. 2911, right column, top) and further discloses glyburide, DIDS, and BSP as inhibitors of ABC1-mediated IL-1beta transport *in vitro* (p. 2913, Figure 1 and p. 2914, Figure 3). However, the specification fails to provide guidance for using glyburide to treat cardiovascular disease. The specification further fails to provide guidance for making other compounds as encompassed by the claims with an expectation that the compounds will have the desired effect of modulating ABCA1 activity and being therapeutically useful in the treatment of cardiovascular disease. While the specification suggests methods for isolating these compounds, such guidance amounts to a trial and error research plan without providing any specific guidance regarding those compounds that are likely to be successful for practicing the claimed method.

The quantity of experimentation needed to make or use the invention based on the content of the disclosure: While methods of therapeutic treatment of a cardiovascular disease were known in the art at the time of the invention, it was not routine to first

identify all compounds having any structure that modulates any biological activity of an ABCA1 polypeptide by a trial and error process. Such experimentation was not routine.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and the significant amount of non-routine experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. As such, applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

[16] Claim(s) 24-28 and 42 are rejected under 35 U.S.C. 102(a) or 35 U.S.C. 102(e) as being anticipated by Whitcomb (US Patent 5,859,037; hereafter, Whitcomb '037) as evidenced by Nieland et al. (*J Lipid Res* 45:1256-1265, 2004). The claims are drawn to a method for treating a mammal having or at risk of developing a cardiovascular disease by administering to said mammal a compound that modulates ABCA1 biological activity.

The reference of Whitcomb '037 teaches that diabetes mellitus is characterized by insulin resistance and is often associated with complications such as cardiovascular disease (column 1, lines 14-17) and thus one having diabetes mellitus would be considered as being at risk of developing a cardiovascular disease." Whitcomb generally teaches a method for treating diabetes mellitus by administering glyburide to a human (column 6).

The reference of Nieland et al. is cited as an evidentiary reference to show that a characteristic not taught in Whitcomb '037 is inherent. Nieland et al. discloses that glyburide modulates biological activity of ABCA1, namely decreasing ABCA1-mediated cholesterol efflux from HEK cells (p. 1261, Figure 4). See MPEP § 2131.01.III regarding multiple reference rejections under 35 U.S.C. 102.

This anticipates claims 24-28 and 42 as written.

The following comments are provided to clarify the record. While the reference of Whitcomb does not teach glyburide inhibits the activity of ABCA1, because Whitcomb administered glyburide, which was shown by Nieland et al. to inhibit ABCA1-mediated cholesterol efflux, inhibition of ABCA1-mediated cholesterol efflux would be an inherent result of practicing the method of Whitcomb. Regarding claims 27-28, while Whitcomb does not teach human ABCA1 has the sequence of SEQ ID NO:1 or amino acids 1-60 of SEQ ID NO:1, because SEQ ID NO:1 is human ABCA1, the method of Whitcomb, which is practiced in a human, would inherently inhibit the ABCA1 of SEQ ID NO:1.

[17] Claim(s) 24-28, 42-43, 45, and 57-62 are rejected under 35 U.S.C. 102(a) or 35 U.S.C. 102(e) as being anticipated by Whitcomb '037 as evidenced by Nieland et al. and further evidenced by Whitcomb (US Patent 5,972,973, hereafter Whitcomb '973). Claim 43 limits the mammal of the method of claim 24 to having low HDL cholesterol relative to normal. Claim 45 limits the mammal of the method of claim 43 to a human.

The reference of Whitcomb '037 discloses the teachings as described above.

The evidentiary reference of Nieland et al. discloses the teachings as described above, namely that glyburide modulates biological activity of ABCA1.

The reference of Whitcomb '973 is cited as a further evidentiary reference to show that a characteristic not taught in Whitcomb '037 is inherent. Whitcomb '973 discloses that "[t]he classical manifestations of insulin resistance in a diabetic population are elevated triglycerides and low levels of HDL" (column 8, lines 29-31). Because the patients treated with glyburide alone or with combination therapy in the method of

Whitcomb '037 are disclosed as having diabetes mellitus, of which a characteristic is insulin resistance (see teachings of Whitcomb '037 above), the patients treated in the method of Whitcomb '037 inherently had low levels of HDL as evidenced by Whitcomb '973.

This anticipates claims 24-28, 42-43, 45, and 57-62 as written.

[18] Claim(s) 24-28, 42, and 49 are rejected under 35 U.S.C. 102(a) or 35 U.S.C. 102(e) as being anticipated by Whitcomb '037 as evidenced by Nieland et al. and further evidenced by Cooper et al. (US Patent 5,260,275). Claim 49 limits the cardiovascular disease of claim 24 to which the mammal has or is at risk of developing to coronary artery disease.

The reference of Whitcomb '037 discloses the teachings as described above.

This anticipates claims 24-28, 42, and 49 as written.

The evidentiary reference of Nieland et al. discloses the teachings as described above, namely that glyburide modulates biological activity of ABCA1.

The reference of Cooper et al. is cited as a further evidentiary reference to show that a characteristic not taught in Whitcomb '037 is inherent. Cooper et al. teaches "[t]he major cause of death and disability in diabetes is coronary artery disease" (column 2, top), thus one having diabetes mellitus would inherently be "at risk" of developing coronary artery disease.

This anticipates claims 24-28, 42, and 49 as written.

[19] Claims 24-26, 28, 41, 43-44, 57-60, and 62 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kamei et al. (*Psychopharmacology* 113:318-321, 1994) as evidenced by Nieland et al. and Whitcomb '973. The claims are drawn to a method for treating a mammal, including a mouse, having or at risk of developing a cardiovascular disease by administering to said mammal a compound that modulates ABCA1 biological activity.

The reference of Kamei et al. teaches administration of glyburide (referred to as gliberclamide in Kamei et al.) to a diabetic mouse (*e.g.,* p. 319, right column, Figure 2).

This anticipates claims 24-26, 41, 43-44, and 57-62 as written.

The reference of Nieland et al. is cited as an evidentiary reference to show that a characteristic not taught in Kamei et al. is inherent. Nieland et al. discloses that glyburide modulates biological activity of ABCA1, namely decreasing ABCA1-mediated cholesterol efflux from HEK cells (p. 1261, Figure 4). While the reference of Kamei et al. does not teach glyburide inhibits the activity of ABCA1, because Kamei et al. administered glyburide, which was shown by Nieland et al. to inhibit ABCA1-mediated cholesterol efflux, inhibition of ABCA1-mediated cholesterol efflux would be an inherent result of practicing the method of Kamei in the diabetic mice.

The reference of Whitcomb '973 is cited as a further evidentiary reference to show that a characteristic not taught in Kamei et al. is inherent. Whitcomb '973 discloses that "[t]he classical manifestations of insulin resistance in a diabetic population are elevated triglycerides and low levels of HDL" (column 8, lines 29-31). Because the mice of Kamei et al. are disclosed as having diabetes, the diabetic mice treated with

glyburide in the method of Kamei et al. inherently had low levels of HDL as evidenced by Whitcomb '973.

While the reference of Kamei et al. does not teach that mouse ABCA1 has amino acids 1-60 of SEQ ID NO:1, the specification discloses that mouse ABCA1 has amino acids 1-60 of SEQ ID NO:1 (p. 49, lines 14-15) and thus, the ABCA1 of the mice of Kamei et al. would inherently have amino acids 1-60 of SEQ ID NO:1.

Claim Rejections - Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[20] The following are provisional obviousness-type double patenting rejections:

- Claims 24-28, 41-45, 49, and 57-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-24 and 26-27 of co-pending US non-provisional application 10/479,198.

- Claims 24-28, 41-45, 49, and 57-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-45 of co-pending US non-provisional application 10/744,465.
- Claims 24-28, 41-45, 49, and 57-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-28 and 32 of co-pending US non-provisional application 10/745,377.
- Claims 24-28, 41-45, 49, and 57-62 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-48 of co-pending US non-provisional application 10/833,679.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '198, '465, '377, and '679 applications either anticipate claims 24-28, 41-45, 49, and 57-62 herein or the specifications of the co-pending applications support an embodiment that would anticipate claims 24-28, 41-45, 49, and 57-62 herein. Claims 24-28, 41-45, 49, and 57-62 of the instant application cannot be considered to be patentably distinct over the claims of the '198, '465, '377, and '679 applications as noted above when there is a specifically recited embodiment

that falls within the scope of claims 24-28, 41-45, 49, and 57-62 herein. Alternatively, claims 24-28, 41-45, 49, and 57-62 cannot be considered to be patentably distinct when there is a specifically disclosed embodiment in the applications that supports the claims and falls within the scope of claims 24-28, 41-45, 49, and 57-62 herein because it would have been obvious to one of ordinary skill in the art to modify the claimed methods in accordance with the teachings of the co-pending applications. One of ordinary skill in the art would have been motivated to do this because those embodiments are disclosed as being a preferred embodiments within the claims. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

[21] The examiner has made an earnest attempt to identify those patents and/or co-pending applications for purposes of rejecting or provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, *e.g.,* cancel claims to preempt a statutory double

patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

Conclusion

[22] Status of the claims:

- Claims 1-62 are pending.
- Claims 1-23, 29-40, 46-48, 50-56 are withdrawn from consideration.
- Claims 24-28, 41-45, 49, and 57-62 are rejected.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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